

In the Claims:

1. (previously presented) A film-shaped therapeutic system comprising at least two layers connected with each other for transmucosal administration of active substances, said at least two layers includes a mucoadhesive layer which is mucoadhesive in an aqueous environment and a backing layer comprising at least one polyacrylate layer and serving as an active substance reservoir, wherein at least one layer of said at least two layers of said system contains an active substance, and wherein said mucoadhesive layer swells in an aqueous media but is insoluble or poorly soluble in the aqueous media and contains a polymer mixture comprising at least one hydrophile, mucoadhesive polymer embedded or dispersed in a polymer matrix comprising at least one polyvinyl alcohol.
2. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said mucoadhesive layer substantially comprises said polymer mixture, said polymer mixture being film-forming, capable of swelling in an aqueous media but is insoluble or poorly soluble in the aqueous media.
3. (currently amended) The film-shaped therapeutic system according to claim 1, wherein said at least one hydrophile, mucoadhesive polymer is selected from the group consisting of carboxyl groups-carrying hydrophile adhesive polymers, polyacrylates, salts of polyacrylates, carboxymethyl cellulose, salts of carboxymethyl cellulose, poly(methyl vinyl ether maleic anhydride), aqueous hydrolysates of poly(methyl vinyl ether maleic anhydride), alcoholic hydrolysates of poly(methyl vinyl ether maleic anhydride)[[.]] and ~~aqueous~~ salts of poly(methyl vinyl ether maleic anhydride) ~~and alcoholic salts of poly(methyl vinyl ether maleic anhydride).~~

4. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said polymer matrix of said mucoadhesive layer is crosslinked by physical or chemical methods.
5. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said at least one polyacrylate layer of said backing layer is a of neutralised polymethyl methacrylate.
6. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said backing layer contains at least one auxiliary substance selected from the group consisting of plasticizers, penetration enhancers, solubilizers, dyes, pigments and matrix formers.
7. (previously presented) The film-shaped therapeutic system according to claim 1, wherein adjacent layers of said system contain at least one identical or chemically allied base polymer.
8. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said system includes 2 to 6 layers.
9. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said the backing layer is a boundary layer for reducing the permeation of water and the diffusion of active substance, relative to the other layer(s) of said system.
10. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said system comprises at least three layers, wherein said at least three layers] comprises a mucoadhesive layer, at least one middle reservoir layer and an outer backing layer, said outer backing layer is a boundary layer for reducing the permeation of water

and the diffusion of active substance, relative to the other layer(s) of said system.

11. (previously presented) The film-shaped therapeutic system according to claim 10, wherein said boundary layer contains additives for reducing or blocking the diffusion of the active substance.

12. (previously presented) The film-shaped therapeutic system according to claim 10, wherein said at least one reservoir layer contains at least one additive for increasing the swelling capacity and the hydration of the reservoir matrix, said at least one additive being a hydrophile, water-binding substance.

13. (previously presented) The film-shaped therapeutic system according to claim 1, wherein said at least one active substance is present in a form selected from the group consisting of dissolved, suspended and emulsified.

14. (previously presented) The film-shaped therapeutic system according to claim 1, wherein at least two layers contain the same active substance at different concentrations under formation of a concentration gradient.

15. (previously presented) The film-shaped therapeutic system according to claim 14, wherein the individual layers contain additives for modifying the solubility and diffusion coefficient of the active substance in the respective layer.

16. (withdrawn) A process for medicinal therapy or prophylaxis comprising the step of applying an active substance-containing film-shaped therapeutic system according to claim 1 onto the oral mucosa of a patient for a period of up to 24 hours for releasing at least one active substance with an initial burst dose and a subsequent maintenance dose.

17. (withdrawn) The process according to claim 16, wherein the release of said at least

one active substance with an initial burst dose and a subsequent maintenance dose takes place for a period of 0.5 hour to 24 hours.

18. (previously presented) The film-shaped therapeutic system according to claim 7, wherein said at least one identical or chemically allied base polymer is a polyacrylate.

19. (previously presented) The film-shaped therapeutic system according to claim 8, wherein said system includes 2 to 4 layers.

20. (previously presented) The film-shaped therapeutic system according to claim 11, wherein said additives for reducing or blocking the diffusion of the active substance is an additive selected from the group consisting of pigments and diffusion-retarding polymers.

21. (previously presented) The film-shaped therapeutic system according to claim 12, wherein said hydrophile, water-binding substance is selected from the group consisting of polyalcohols and polymeric surfactants with an HLB value of  $\geq 10$ .

22. (withdrawn) A process for medicinal therapy or prophylaxis according to claim 16, wherein the step of applying an active substance-containing film-shaped therapeutic system according to claim 1 onto the oral mucosa of a patient is for a period of up to 6 hours.